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Kathy Hinckley

PATENT

Applicant:	George Martinez
Serial No.:	10/631,981
Filed:	July 31, 2003
Title:	**THREE ELEMENT COAXIAL VASO-OCCLUSIVE DEVICE**
Examiner:	Elizabeth Houston
Group Art Unit:	3731
Confirmation No.:	2212
Atty. Docket No.:	388700-612-11-PA

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

REPLY BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Examiner's Answer to Appeal Brief mailed January 15, 2010, please consider the Reply Brief contained herein.

The Commissioner is authorized to charge any additional filing fees or credit any overpayment to Deposit Account No. 50-2809.

STATUS OF CLAIMS

Claims 1-67 are currently pending and of these claims, claims 1,14, 29, 40, 52, 66 and 67 are independent. Claims 1-67 are rejected based on prior art. Claims 1-67 are currently being appealed.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection to be reviewed on appeal is the Examiner's rejection of claims 1-67 under 35 U.S.C. Section 103(a). The Examiner contends that these claims are unpatentable over U.S. Publication No. 2002/0169473 to Sepetka ("*The Sepetka Publication*") in view of U.S. Patent No. 7,006,904 to Rosenthal ("*The Rosenthal Patent*") in further view of PCT Pub. No. WO 98/01421 to Kopecek ("*The Kopecek Publication*").

ARGUMENT

I. INDEPENDENT CLAIMS 1, 14, 29, 40, 52, 66 AND 67

Filling an Aneurysm

In the Appeal Brief filed November 4, 2009, the Appellant argued that *The Sepetka Publication* cannot be positioned within an aneurysm and therefore cannot fill an aneurysm since its size, shape, configuration and flexiblitly would prevent any kind of entry into the aneurysm. Further, attempts to place the stiff Sepetka device in an aneurysm would almost certainly rupture the aneurysm.

In the Examiner's Answer dated January 15, 2010, the Examiner argues that the "claimed recitation does not require that the device be positioned within the aneurysm, but rather requires that the expansile element be *capable* of expanding to fill the aneurysm." The Examiner further cites Fig. 69 of *The Sepetka Publication* which shows a device within a malformed vessel, asserting that if there was a hydrogel coating on the inner coils 352, it must at least partially expand into the malformation.

It is unclear in Fig. 69 where the diameter of the vessel stops and where the diameter of the malformation starts. Further, *The Rosenthal et al. Patent* only discloses a thin hydrogel layer of unspecified thickness that could swell or contract by unspecified amounts to release drugs. Therefore, it is not clear that a hypothetical hydrogel coating would actually expand into the malformed diameter region as the Examiner asserts. Hence, the Examiner has provided no factual basis that such a hypothetical would function as asserted.

Kopacek Does Not Teach Material that can expand at a controlled rate in an Aneurysm

In the Appeal Brief filed November 4, 2009, the Appellant argued that the hydrogel of *The Kopecek Publication* was narrowly tailored to survive various hostile environments of the intestinal tract, then releases drugs by a combination of swelling and enzymatic degradation in the colon. Since the enzymatic and pH level of the blood

are dramatically different than that of the colon or other areas of the intestine, the Kopecek hydrogel would not be capable of expanding at a controlled rate to fill an aneurysm as claimed.

In the Examiner's Answer dated January 15, 2010, the Examiner apparently acknowledges our argument that the Kopecek hydrogel is not capable of expanding at a controlled rate to fill an aneurysm as claimed. However, the Examiner further argues that *The Kopecek Publication* is merely used to show that pH-triggered expansion is at least known and therefore it would be obvious to one of ordinary skill in the art to modify this hydrogel for expanding at a controlled rate to fill an aneurysm.

First, this line of arguments impermissibly ignores claim language. The claims differently recite that an expansile intermediate is capable of expanding at a controlled rate to fill an aneurysm, not simply to expand at a controlled rate. In this respect, the Examiner parses the claim language to such an extent that the original meaning of the claim is unrecognizable. The Examiner is reminded that "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

Second, with all due respect, the Examiner makes an unsupported factual assumption with this argument. Namely, that since the prior art teaches how to design hydrogel to swell within a colon via pH and enzymes, it must have been known how to cause hydrogel (or similar expandable material) to expand at a controlled rate to fill an aneurysm. The Examiner provides no references or other technical support that demonstrate that someone skilled in the art could adapt the teaching of *The Kopecek Publication* to expand at a controlled rate to fill an aneurysm.

As previously discussed in the Appeal Brief, the environment in the colon and an aneurysm are dramatically different and therefore different formulations and preparations of an expansile element such as hydrogel are required. Further, material and chemical sciences are not necessarily linear or predictable, especially with regard to complex environments within the body. For example, the pH, type and level of enzymes, temperature, water content, and other mineral/chemical contents widely vary

from location to location in the body. Hence, the Examiner has provided no support that the Kopacek hydrogel could be adapted by one of ordinary skill in the art to expand at a controlled rate to fill an aneurysm.

Hence, *The Kopecek Publication* does not teach or make obvious a material that can expand at a controlled rate to fill an aneurysm.

***Kopecek* Does Not Teach a Controlled Rate of Expansion**

In the Appeal Brief filed November 4, 2009, the Appellant argued that *The Kopecek Publication* only discloses a "triggering pH" mechanism that initiates expansion of hydrogel but not the ability to control the rate that the swelling occurs.

In the Examiner's Answer dated January 15, 2010, the Examiner apparently admits that once the Kopecek hydrogel begins expanding, there is no mechanism in place to control or otherwise limit the speed that this hydrogel expands. However, the Examiner argues that this is "irrelevant" because "any rate of expansion is considered a controlled rate of expansion since there are no structural limitations in the claims directed toward what element is controlling the rate."

With all due respect, the Examiner's argument again impermissibly ignores or misinterprets claim language. The claims recite expanding at a *controlled* rate, not expanding at an uncontrolled rate. In other words, the Examiner is effectively interpreting "controlled rate" to include expansion where no control is present. This is contrary to the clear meaning of the words in the claims and the description in the specification. It is noted that the Examiner has provided no evidence to support how "any rate of expansion is considered a controlled rate".

Further, the specification provides clear support for the Appellant's interpretation of "controlled rate" by describing example expansion rate control mechanisms, such as in the example hydrogel preparations of paragraphs 0024-0033 of the present Application. Further, paragraph 0033 of the present invention states:

> If pH sensitive monomers with amine groups were incorporated into the hydrogel network, the hydrogel is incubated in high pH solution.

> Deprotonation occurs on the amine groups of the hydrogel network at high pH. **The duration and temperature of the incubation, and the pH of the solution, influence the amount of control on the expansion rate. Generally, the duration, temperature, and solution pH of the incubation are directly proportional to the amount of expansion control**...[emphasis added]

In other words, the specification provides much discussion and guidance about how expanding at a controlled rate involves a specific mechanism which can be manipulated or adjusted by a manufacture (e.g., a preparation process of hydrogel). The Appellant can find no such discussion in *The Kopecek Publication* about such a rate controlling mechanism. Hence, the Examiner's argument that any rate of expansion represents a controlled rate lacks merit.

***Prima Facie* Case of Obviousness**

In the Appeal Brief filed November 4, 2009, Appellant argued that the Examiner's *prima facie* case of obviousness was flawed because it relied on a conclusory and unsupported rationale for combining the references. More specifically, the Examiner's argument that combining the references would be desirable for delivering drugs ignored that drug delivery was not recited in the claims and that such drug delivery was unsupported conclusory speculation.

In the Examiner's Answer dated January 15, 2010, the Examiner argues that "the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious." In other words, the Examiner apparently argues that the prior art does suggest combination of the prior art references, but does not provide any support or details.

First, it should again be emphasized that the Examiner has not cited any teaching, suggestion or motivation to combine the references. The Examiner simply states that such a combination would be possible for drug delivery, but completely ignores the reasoning or rationale about why one of ordinary skill in the art would select

the specific elements and configuration recited in the claims. There are many ways to deliver drugs to a patient. Why would a user select this configuration for drug delivery?

Second, the Examiner has ignored that "a prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention" and therefore the combination of the cited references would not function as the Examiner asserts (WL Gore v. Garlock 721 F.2d 1540, USPQ 303, emphasis in original).

The device of Figs. 62-69 of *The Sepetka Publication* and cited by the Examiner show main coils 352, which the Examiner argues could be combined with an expandable hydrogel coating. Then, a dense mesh 358 is located over the main coils 352 to isolate an aneurysm from the vessel (i.e., block passage into the aneurysm). It would be illogical for one of ordinary skill in the art to place a hydrogel coating on the main coils 352 when it would be isolated by the dense mesh 358 from the vessel. Further, a hydrogel coating on the main coils 352 would expand inward within healthy portions of the vessel, occluding the healthy portions of the vessel and causing serious complications such as a stroke. Hence, it would be extremely dangerous to use a Sepetka stent with a hydrogel coating on the main coils 352.

If one was especially interested in delivering drugs, as the Examiner suggest the motivation would be, then one of ordinary skill in the art would place the drug releasing coating on the outermost layer of the device (i.e., the dense mesh 358), so as to allow the drug to best enter the vessel. However, this configuration risks occluding the vessel too, and therefore would not be a logical choice for one of ordinary skill in the art.

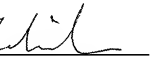
In this respect, *The Sepetka Publication* teaches away from a combination of elements similar to the pending claims. Again, the Examiner provides no alternate logic, rationale or support for why this teaching away in *The Sepetka Publication* is incorrect or should be ignored.

IV. CONCLUSION

For at least all the reasons stated herein, it is submitted that the Examiner's rejections are erroneous. As a result, the Applicant's seek a reversal of the Examiner's rejection on this appeal. Reversal is hereby affirmatively requested.

Respectfully submitted,

Dated: March 15, 2010



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